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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,421	BRUEGGER, BERNDT B.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 8 of claim 16, the phrase "said heparin therapy" lacks antecedent basis since a "heparin treatment" was previously positively recited in the claim.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by CA 1,250,213 (submitted in the Information Disclosure Statement filed on September 18, 2003).

CA 1,250,213 teaches of a reagent for use in performing an activated partial thromboplastin time test (APTT) on a blood sample, which comprises a phospholipid and an activator. The activator can be a sulfatide or a mixture of sulfatides. The reagent comprises a 1:1 ratio of the phospholipid (i.e. a phosphatide) and the sulfatide. See the example on page 10 of CA 1,250,213. The reagent also comprises a buffer, and can be freeze-dried. Since CA 1,250,213 teaches the same weight ratio of sulfatide to phosphatide as recited in instant claim 30, the reagent taught by CA 1,250,213 would inherently perform the same function of determining heparin treatment effectiveness, especially when a patient's heparin level is 0 U/ml, which is a possible heparin level recited in claim 30. The situation when a patient's heparin level is 0 U/ml is equivalent to the APTT clotting test taught by CA 1,250,213 on blood samples not having heparin therein.

4. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Bader et al (abstract, submitted in the Information Disclosure Statement filed on September 18, 2003).

Bader et al teach of a reagent comprising recombinant human tissue factor and synthetic phospholipids (i.e. phosphatidyl choline and phosphatidyl serine). Therefore, the reagent taught by Bader et al comprises tissue factor and at least one co-factor selected from the group consisting of a phosphatide (i.e. the synthetic phospholipids) and a sulfatide. The reagent taught by Bader et al can inherently be used to determine the effectiveness of heparin therapy in a patient by measuring clotting time, as recited in instant claim 16, since the reagent taught by Bader et al is for the determination of prothrombin clotting time in blood samples and claim 16 does not recite a concentration of heparin in the patient's blood, thus allowing the possibility that no heparin is present in the patient's blood, which is equivalent to the determination of clotting time in regular blood samples containing no heparin, as taught by Bader et al.

5. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gailani et al (submitted in the Information Disclosure Statement filed on September 18, 2003).

Gailani et al teach of a method and a reagent used to determine the clotting time of a blood sample. In the method, a blood sample is combined with tissue factor, and then clot formation is initiated by the addition of calcium chloride in a 1:10 dilution of rabbit brain cephalin with 1 mmol/L of a bovine brain sulfatide. Rabbit brain cephalin is a type of a phosphatide since it is a phospholipid (i.e. phosphatidylethanolamine). Therefore, the reagent combined with the blood sample in the method of Gailani et al comprises tissue factor, a phosphatide and a sulfatide. See the second column on page 814 of Gailani et al. The reagent taught by Gailani et al can inherently be used to determine the effectiveness of heparin therapy in

a patient by measuring clotting time, as recited in instant claims 1 and 16, since the reagent taught by Gailani et al is for the determination of clotting time in blood samples, and claim 1 recites that the heparin concentration in the patient's blood can be "up to 6 U/ml" which could be interpreted to mean a concentration of 0 U/ml, while claim 16 does not recite a concentration of heparin in the patient's blood, thus allowing the possibility that no heparin is present in the patient's blood. Both situations included within the scope of claims 1 and 16 are equivalent to the determination of clotting time in regular blood samples containing no heparin, as taught by Gailani et al.

6. Claims 16 and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al (WO 96/15457, submitted in the Information Disclosure Statement filed on September 18, 2003).

Griffin et al teach of a method for the diagnosis of thrombotic disorders, wherein the clotting time of a test sample of blood is analyzed in the presence and absence of activated protein C (APC). The method is based upon a procoagulant reagent-dependent factor V coagulation assay. The procoagulant reagent refers to any type of reagent that serves as an activator of the intrinsic coagulation pathway. The procoagulant includes activators such as kallikrein and APTT reagent (i.e. a reagent containing a phospholipid and a contact activator such as a sulfatide). Griffin et al teach that the procoagulant is preferably a tissue factor, either from bovine brain or recombinant. The tissue factor may intrinsically include phospholipid or phospholipid may be exogenously included in the test sample. Any type of procoagulant phospholipid can be used. See page 8 of Griffin et al. Griffin et al use the procoagulant reagent to test plasma samples containing heparin in a final concentration of 0.5 U/ml. See example 4 on

page 18 of Griffin et al. Therefore, Griffin et al teach of a method and reagent for determining the clotting time in blood samples containing heparin in a low dose by combining the blood sample with a reagent containing tissue factor and a phosphatide. Griffin et al also inherently teach of a reagent comprising tissue factor and a cofactor, wherein when an effective amount of the reagent is contacted with a blood sample having a heparin level between 0 and 6 U/ml, a predetermined degree of clotting is reached in less than 300 seconds, since the reagent taught by Griffin et al (i.e. a tissue factor and a phosphatide) is the same as in the instant invention which performs this function, and the blood sample in Griffin et al whose clotting time is measured contains a heparin level of 0.5 U/ml, which is included in the scope of instant claim 16 that does not recite a specific concentration of heparin in the patient's blood, and in the scope of instant claims 33-34 that recite a heparin concentration in the patient's blood between 0 and 6 U/ml.

7. Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by McDonald et al (US Patent no. 5,039,617, submitted in the Information Disclosure Statement filed on September 18, 2003)

McDonald et al teach of a capillary flow device, method and reagent for measuring activated partial thromboplastin time (APTT). The reagent used comprises a mixture of an activating agent for APTT measurements, usually a bovine sulfatide, and phospholipids such as phospholipid extracts of mammalian brain (i.e. a phosphatide). The two components of the reagent are usually present in proportions such that when using a sulfatide as the activator, the activator is typically present at 0.1 to 1 times the weight amount of the phospholipid, and preferably about 0.5 times the weight amount of the phospholipid. See lines 17-61 in column 10 of McDonald et al. The test is used to measure APTT for blood samples containing a heparin

concentration of about 0.1 U/ml and 0.3 U/ml. See example 3 in column 16 of McDonald et al. McDonald et al also teach that other components may be present in the reagent, such as a buffer and stabilizing agents. The device containing the reagent and used to perform the method is described on lines 40-68 of column 13 and lines 1-26 of column 14 in McDonald et al. See also Figures 1A and 1B. The device comprises an inlet port, a first capillary unit connecting the inlet port to a chamber unit, a second capillary unit for connecting the chamber unit to an exit port, and an exit port. The reagent composition is present in the capillary pathway so as to become dissolved in and mixed with a blood sample applied to the device. Therefore, McDonald et al teach of a reagent composition containing therein a sulfatide and a phosphatide in a weight ratio of 1:1 or 1:2. Since McDonald et al teach the same weight ratio of sulfatide to phosphatide as recited in instant claim 30, the reagent taught by McDonald et al would inherently perform the same function of determining heparin treatment effectiveness in patients having blood heparin levels of between 0-6 U/ml, since McDonald et al teach of the use of the reagent for the determination of clotting time in blood samples containing some level of heparin therein which is greater than 0, i.e. a heparin level of 0.1 U/ml or 0.3 U/ml.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gailani et al. For a teaching of Gailani et al, see previous paragraphs in this Office action.

Gailani et al fail to teach of the concentration levels of the tissue factor and sulfatide in the clotting reagent, fail to teach of freeze-drying the reagent, and fail to teach of the addition of buffers and stabilizing agents to the reagent. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to vary the concentration levels of the tissue factor and sulfatide in the reagent taught by Gailani et al to the levels recited in the instant claims since concentration is a result effective variable that can be varied depending upon a desired intended use of the composition, and for optimization of a procedure being performed. It also would have been obvious to one of ordinary skill in the art to freeze-dry the reagent and add a buffer and stabilizing agents to the reagent taught by Gailani et al in order to preserve the reagent for an extended shelf life.

11. Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. For a teaching of Griffin et al, see previous paragraphs in this Office action.

Griffin et al fail to teach of the concentration levels of the tissue factor and phosphatide in the procoagulant reagent, fail to teach of freeze-drying the reagent, and fail to teach of the addition of buffers and stabilizing agents to the reagent. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to vary the concentration levels of the tissue factor and phosphatide in the reagent taught by Griffin et al to the levels recited in

the instant claims since concentration is a result effective variable that can be varied depending upon a desired intended use of the composition, and for optimization of a procedure being performed. It also would have been obvious to one of ordinary skill in the art to freeze-dry the reagent and add a buffer and stabilizing agents to the reagent taught by Griffin et al in order to preserve the reagent for an extended shelf life.

12. Claims 8-15, 23-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald et al in view of Gailani et al. For a teaching of McDonald et al and Gailani et al, see previous paragraphs in this Office action.

McDonald et al fail to teach that the capillary flow device can contain therein a reagent comprising tissue factor and a sulfatide. However, based upon the combination of McDonald et al and Gailani et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include in the capillary flow device taught by McDonald et al the reagent taught by Gailani et al containing a tissue factor and a sulfatide, since McDonald et al disclose that the reagent in the capillary flow device must serve to activate the intrinsic coagulation pathway of blood, and Gailani et al teach that the combination of a tissue factor and a sulfatide serves to activate the intrinsic coagulation pathway of blood. It also would have been obvious to one of ordinary skill in the art to vary the concentration levels of the tissue factor and sulfatide in the reagent taught by Gailani et al to the levels recited in the instant claims since concentration is a result effective variable that can be varied depending upon a desired intended use of the composition, and for optimization of a procedure being performed.

13. Claims 23-29 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald et al in view of Griffin et al. For a teaching of McDonald et al and Griffin et al, see previous paragraphs in this Office action.

McDonald et al fail to teach that the capillary flow device can contain therein a reagent comprising tissue factor and either a phosphatide or a sulfatide. However, based upon the combination of McDonald et al and Griffin et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include in the capillary flow device taught by McDonald et al the reagent taught by Griffin et al containing a tissue factor and a phosphatide, since McDonald et al disclose that the reagent in the capillary flow device must serve to activate the intrinsic coagulation pathway of blood, and Griffin et al teach that the combination of a tissue factor and a phosphatide serves to activate the intrinsic coagulation pathway of blood. It also would have been obvious to one of ordinary skill in the art to vary the concentration levels of the tissue factor and phosphatide in the reagent taught by Griffin et al to the levels recited in the instant claims since concentration is a result effective variable that can be varied depending upon a desired intended use of the composition, and for optimization of a procedure being performed.

14. Applicant's arguments filed October 25, 2004 have been fully considered but they are not persuasive.

Applicant argues the rejection of claim 30 under 35 USC 102(b) as being anticipated by CA 1,250,213 by stating that there is no teaching or suggestion in the CA patent of relating clotting times to heparin treatment effectiveness, or suitable reagents for performing such an assay. Applicant argues that the Examiner has not shown any rationale or evidence for inherency in the CA teaching, and that the CA patent does not teach or suggest a reagent which can

determine heparin treatment effectiveness. In response to these arguments, it is first noted that claim 30 is directed to a reagent composition having as ingredients therein a sulfatide and a phosphatide in the recited weight ratios. Claim 30 does not recite an assay or method for determining heparin treatment effectiveness based upon the clotting of blood. Therefore, the only patentable limitations in claim 30 are the sulfatide and phosphatide in the recited weight ratios. Because the CA patent teaches of a composition containing a sulfatide and a phosphatide in the recited weight ratios, this patent anticipates claim 30 since it contains each and every one of the patentable limitations recited within claim 30. The recitation of the heparin treatment, which affects the clotting of blood in a patient in claim 30, is merely an intended use of the reagent. This new limitation added to claim 30 does not further limit the chemical make-up of the reagent composition itself. It merely further limits the intended use of the reagent composition, which has no patentable bearing on the composition itself. A statement of the intended use of a composition in a composition claim or the fact that a composition is intended for a new and unobvious purpose does not render the composition patentable. An intended use does not create patentability of an otherwise old or suggested composition. See In re Pearson, 181 USPQ 641 (CCPA 1974). With regards to showing a rationale or evidence for inherency in the CA patent, the Examiner points to the fact that the composition taught by the CA patent is the same as the composition recited in instant claim 30 (i.e. a sulfatide and a phosphatide), and therefore, would be expected by one of ordinary skill in the art to behave the same in a particular assay or environment. It would be expected that the CA composition would perform the same functional limitations as recited in claim 30 since the chemical make-up of the composition taught by the CA patent is no different than the composition recited in claim 30.

Applicant argues the rejection of claim 16 under 35 USC 102(b) as being anticipated by Bader et al by again stating that Bader et al do not teach or suggest the relationship between clotting times and heparin treatment effectiveness, or suitable reagents and cartridges for performing such an assay. In response to this argument, it is again noted that claim 16 does not recite an "assay", but rather a reagent comprising tissue factor and either a sulfatide or a phosphatide. Since Bader et al teach of a composition containing the same chemical ingredients as the composition recited in claim 16, the teaching of Bader et al anticipates claim 16. The functional recitations of determining heparin treatment effectiveness, and the relationship between clotting times and heparin treatment do not further limit the chemical composition of the reagent recited in claim 16, and therefore, do not further patentably distinguish this composition from Bader et al.

Applicant argues the rejection of claims 1 and 16 under 35 USC 102(b) as being anticipated by Gailani et al by again stating that Gailani et al do not teach or suggest the relationship between clotting times and heparin treatment effectiveness, or suitable reagents and cartridges for performing such an assay. In response to this argument, it is again noted that claims 1 and 16 do not recite an "assay", but rather a reagent comprising tissue factor and either a sulfatide or a phosphatide. Since Gailani et al teach of a composition containing the same chemical ingredients as the composition recited in claims 1 and 16, the teaching of Gailani et al anticipates claims 1 and 16. The functional recitations of determining heparin treatment effectiveness, and the relationship between clotting times and heparin treatment do not further limit the chemical composition of the reagent recited in claims 1 and 16, and therefore, do not further patentably distinguish this composition from Gailani et al.

Applicant argues the rejection of claims 16 and 33-34 under 35 USC 102(b) as being anticipated by Griffin et al by stating that Griffin et al do not teach each and every element of these claims since they teach away from the determination of the effectiveness of heparin treatment because in the method of Griffin et al, heparin is viewed as an interferant that has no impact on the test results. In response to these arguments, it is again noted that Applicant is arguing that the intended use of the composition taught by Griffin et al is different than the intended use of the composition recited in instant claims 16 and 33-34. Since claims 16 and 33-34 are claims directed to reagent compositions, the only patentable limitations in these claims are the recited chemical components in the compositions, i.e. a tissue factor and a cofactor. Since Griffin et al teach of a composition containing each and every one of these chemical components, the disclosure of Griffin et al anticipates claims 16 and 33-34. The amendment to the claims concerning the heparin treatment affecting the clotting time of a blood sample from a patient does not further limit the chemical composition of the claims. Rather, this amendment only serves to further limit the method or assay intended to be performed with the reagent composition.

Applicant argues the rejection of claim 30 under 35 USC 102(b) as being anticipated by McDonald et al by stating that the McDonald et al patent is directed to a different assay, and does not teach or suggest a reagent that can determine heparin treatment effectiveness in patients receiving heparin. In response to this argument, it is noted that instant claim 30 does not recite an "assay", but rather recites a reagent composition. Applicant's argument treats claim 30 as if it were an assay or method claim by putting patentable weight on the steps of determining heparin treatment effectiveness by determining the clotting of blood in a patient receiving heparin.

These steps are merely an intended use of the reagent composition. When the heparin level of the patient's blood analyzed with the method of McDonald et al is zero, the reagent taught by McDonald et al anticipates claim 30 since it comprises a sulfatide and a phosphatide, and is used in a blood-clotting assay.

Applicant argues the rejection of the claims under 35 USC 103 as being obvious over either Gailani et al or Griffin et al by stating that it would not be a matter of routine experimentation to vary the concentration levels of the tissue factor and cofactors taught in the compositions of Gailani et al and Griffin et al to the levels recited in the instant claims since these references do not teach or suggest the relation between clotting times and heparin treatment effectiveness. In response to this argument, it is again noted that the claims are directed towards reagent compositions containing therein tissue factor and a cofactor, not to an assay or method for determining heparin treatment effectiveness based upon blood clotting. Both references to Gailani et al and Griffin et al teach of compositions containing the same chemical ingredients as recited in the instant claims. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges for a specific purpose by routine experimentation. See In re Aller et al, 105 USPQ 233 and In re Reese, 129 USPQ 402.

Applicant argues the rejection of the claims under 35 USC 103 as being obvious over McDonald et al in view of either Gailani et al or McDonald et al in view of Griffin et al by stating that McDonald et al fail to teach of a test cartridge wherein clotting time is used to determine the effectiveness of heparin treatment in a patient receiving heparin treatment, and wherein the heparin treatment affects clotting time of a blood sample from a patient. In response to this argument, McDonald et al do teach of the same type of test cartridge as recited in the

instant claims since the device taught by McDonald et al contains a housing having an inlet port, a chamber unit, and an exit port, wherein a reagent is present in the capillary pathway for initiating the coagulation of blood. The reagent contains both a phosphatide and a sulfatide. Since the instant test cartridge claims are directed to an apparatus and not a method, the only patentable limitations in these claims are the housing containing the inlet port, chamber unit and exit port as a capillary channel, and the reagent composition held within the capillary channel of the housing. The cartridge taught by McDonald et al contains all of the same physical features as recited in the instant test cartridge claims with the exception of the reagent composition held within the capillary channel. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include in the capillary flow device taught by McDonald et al the reagent taught by either Gailani et al or Griffin et al containing a tissue factor and a cofactor, since McDonald et al disclose that the reagent in the capillary flow device must serve to activate the intrinsic coagulation pathway of blood, and both Gailani et al and Griffin et al teach that the combination of a tissue factor and a cofactor serves to activate the intrinsic coagulation pathway of blood. The intended use of the test cartridge recited in the instant claims for determining the effectiveness of heparin treatment in a patient is given no patentable weight in an apparatus claim. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitations of that claimed.

In conclusion, Applicant notes that the parent application serial no. 09/645,786 was allowed since none of the prior art taught or suggested a method for determining the effectiveness of heparin treatment in a patient receiving doses of heparin of up to about 6 U/ml

by determining the clotting time of a blood sample from the patient, wherein the clotting time is altered by the heparin treatment, and wherein the blood sample is contacted with one of the recited reagents. Applicant argues that since the parent claims were allowed for the stated reasons and the instant reagent and test cartridge claims recite the same limitations, these instant claims should also be allowed. In response to this argument, it is noted that the claims in the parent application only recited a method or assay, which is patentable over the cited prior art of record for the reasons given. The instant claims in this application only recite a reagent or a test cartridge, where the intended use of both are not given patentable weight. In order for these claims to be patentable over the prior art of record, something in the chemical components or ingredients of the reagent composition, or something in the physical components of the cartridge must be different than the prior art in order to define over the cited prior art. At the present time, other than a functional intended use, neither the reagent nor the test cartridge claims recite any structural or chemical features that define them over the cited prior art of record. For these reasons, Applicant's arguments are not found persuasive.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

January 11, 2005

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700